

*REMARKS**Discussion of Claim Amendments*

Claims 1 and 25 have been amended to recite that the salivation promoting agent is "selected from water-soluble organic acids, sodium hydrogen tartrate, potassium hydrogen tartrate and sodium hydrogen citrate". The claim amendment is supported by the original specification, e.g., at page 13, lines 23-30. Claim 9 was amended so that the claim language is consistent with the amendment to claim 1.

Claims 1 and 25 also have been amended to recite that the hydratable polymer is an "ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa·s and selected from the group consisting of sodium carboxymethylcellulose, sodium carboxymethyl starch, polyacrylic acid, polyacrylate, alginic acid, alginate, pectin, xanthan, galactomannan, guar gum, hydroxypropyl-guar gum, gelatin and gum arabic". This is supported by page 14, line 30 to page 15, line 16; sodium carboxymethyl starch is named on page 43, line 3 and on page 44, line 20. The feature that the polymer is "ionic" implies that at least part of the carboxyl moieties contained in all these polymer are in the form of ionic carboxylate.

Claims 1 and 25 have been further amended to specify that the particle paste is "a consistent, coherent, soft, mouldable, viscous particle paste in which the particles are stuck together". This is supported by page 31, lines 14-22 of the specification.

Claim 2 has been amended such that it now indicates the nonionic alternative of the hydratable polymer present *in addition* to the ionic polymer present according to claim 1. This is supported by page 14, line 22 to page 15, line 10; page 19, lines 13-25; example 2 (ionic polymer xanthan powder, nonionic polymers polyvinylpyrrolidone and hydroxypropylmethyl cellulose); example 3 (ionic polymer sodium carboxymethylcellulose; nonionic polymers hydroxypropylmethyl cellulose, hydroxyethylcellulose and hydroxypropylcellulose); example 8 (ionic polymer sodium alginate; nonionic polymers polyvinylpyrrolidone and hydroxypropylcellulose); example 9 (ionic polymer xanthan powder; nonionic polymers methylcellulose and microcrystalline cellulose); example 10 (ionic polymers sodium carboxymethylcellulose and sodium carboxymethyl starch; nonionic polymers

hydroxypropylmethylcellulose, polyvinylpyrrolidone); example 11 (ionic polymer sodium carboxymethyl cellulose; nonionic polymer polyvinylpyrrolidone); example 12 (ionic polymer sodium carboxymethyl starch; nonionic polymers microcrystalline cellulose, polyvinylpyrrolidone and hydroxypropylmethylcellulose); and example 13 (ionic polymer sodium carboxymethylcellulose; nonionic polymers hydroxyethylcellulose and polyvinylpyrrolidone).

No new matter has been added by way of these amendments.

*Discussion of Rejections*

*A. Anticipation Rejection*

Claims 1, 3, 8, 9, 15-17, and 25 are rejected under 35 USC 102(b), as allegedly anticipated by U.S. 5,178,878 (Wehling).

Although Applicant disagrees with the rejection, Applicant has amended the claims, as discussed, to expedite the prosecution of the present application. Applicant respectfully submits that Wehling fails to anticipate the presently claimed invention.

Amended claims 1 and 25 now require that the coating present on the coated particles, or, in the case of several coating layers, the outermost coating layer contains a salivation-promoting water soluble organic acid, sodium hydrogen tartrate, potassium hydrogen tartrate or sodium hydrogen citrate. This means that these compounds are ingredients of the coating material. In contrast thereto, Wehling does not disclose any water soluble organic acids or salts thereof as possible ingredients of the protective material, and insofar as the protective material is a carboxylic acid-containing polymer, such as the carboxymethylcellulose noted by the Office Action, acrylic resin, polypeptides, or proteinaceous materials, that polymer is not a salivation-promoting agent, as required by amended claims 1 and 25. Furthermore, Wehling's protective material is not necessarily a coating on the microparticles; it may also serve as a mere matrix for the active agent (column 2, lines 32-39; column 9, lines 42-63).

In Wehling's formulation, a food acid or salt thereof may be present in the effervescent disintegrating agent, as observed by the Office Action (bridging paragraph columns 5/6). This effervescent disintegrating agent is, however, only *mixed* with the

microparticles (column 2, lines 22-25 and lines 42-45), *not coated* on the microparticles. As already stated amended claims 1 and 25 require that the water-soluble organic acid sodium hydrogen tartrate, potassium hydrogen tartrate or sodium hydrogen citrate be contained in a *coating* layer on the particles.

To anticipate a claim, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988). The elements in the reference must be arranged as in the claim under review. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984). The cited reference Wehling fails to disclose every element of the claimed invention. Accordingly, Applicant respectfully submits that amended claims 1 and 25, as well as claims 8, 9, 15 and 16 depending from claim 1, are novel over Wehling.

In regards to claims 1 and 25, the Office Action states that the limitation that upon the composition coming in contact with saliva it forms a “coherent, moldable, viscous particle paste which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the particle paste, and release of active ingredient in the mouth” is an inherent property of the composition, and that “where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case for either anticipation or obviousness has been established.”

Applicant respectfully submits that the aforesaid limitation should be afforded full patentable weight and not dismissed as an inherent property. Moreover, in view of the claim amendment, the presently claimed invention is novel over the cited references as discussed above. Applicant also submits that the claimed invention is non-obvious as discussed herein below. In view of the foregoing, Applicant respectfully requests the Examiner to give patentable weight to the limitation of promoting a flow of saliva which is sufficient to form a consistent, coherent, soft, moldable, viscous particle paste in which the particles are stuck together, which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the particle paste, and release of active ingredient in the mouth (as presently amended).

*B. Obviousness Rejections*

1. Claims 7 and 23

Claims 7 and 23 are rejected under 35 USC 103(a), as allegedly unpatentable over Wehling. Claims 7 and 23 are dependent upon claim 1, which has been amended. Applicant respectfully submits that the obviousness rejection has been rendered moot in view of the claim amendment.

As discussed, amended claim 1 is novel over Wehling because a water-soluble organic acid, sodium hydrogen tartrate, potassium hydrogen tartrate or sodium hydrogen citrate is required as an ingredient in the coating, whereas Wehling has the organic acid only as a part of the effervescent disintegration agent not forming a coating (see above). In the Applicant's view, the skilled person would not incorporate Wehling's acid-containing effervescent disintegration agent into his protective material: Such effervescent protective material would upon contact with saliva and formation of gas bubbles (see column 1, lines 22-23) either tear apart the microparticles, if the protective material was the matrix of the microparticles; or blow off their coating, if the protective material was the coating on the microparticles. This would make the taste-masking sought by Wehling (see abstract and column 4, lines 6-10) impossible. Accordingly, there is no motivation to modify Wehling to arrive at the presently claimed invention.

Furthermore, since Wehling's formulation contains an effervescent *disintegration* agent, it largely *disintegrates* upon contact with saliva into individual microparticles. This is the opposite of the teaching of instant claim 1, which requires that the particles form a coherent particle paste in which the particles are stuck together after contact with saliva. Thus, Wehling teaches away from the presently claimed invention.

Even furthermore, Wehling states, in regards to the food acids contained in the effervescent disintegration agent, that "their overall solubility in water is less important" (column 6, lines 3-7), whereas instant claims 1 and 25 require mandatorily that the organic acid be "water soluble".

Concerning claim 23, it is not disputed that Wehling teaches that its formulation can be taken without chewing. Wehling, however, attributes the superfluousness of chewing to the

effervescence of his formulation (column 3, lines 8-10; column 4, lines 6-7). In the Applicant's view the skilled person would not provide Wehling's formulation with instructions that it be taken without chewing, if that formulation was lacking the effervescent disintegration agent. Claim 23, being dependent upon claim 1, requires that there be a coherent particle paste where the particles stick together even after contact with saliva (i.e. no effervescence is allowed, see above), is thus not obvious from Wehling for this further reason either.

In view of the foregoing, the obviousness rejection of claims 7 and 23 should be withdrawn.

## 2. Claims 2, 4, 10, 11, and 12

Claims 2, 4, and 10-12 are rejected under 35 USC 103(a), as allegedly unpatentable over Wehling in view of US 4,122,157 (Huber). Applicant respectfully submits that the rejection is untenable.

Firstly, neither Wehling nor Huber discloses a coated particle, wherein the coating or outermost layer of the coating contains a salivation-enhancing water soluble organic acid, sodium hydrogen tartrate, potassium hydrogen tartrate or sodium hydrogen citrate.

Accordingly, amended claim 1 and claims 2, 4, 10, 11 and 12 depending from it are thus inventive over these documents for this formal reason alone.

Further, while Wehling teaches effervescent compositions, as well as Huber, effervescence is not allowed in the composition of the instant amended claims due to the feature of the coherent particle paste where the *particles are stuck together* on contact with saliva. In this regard, Wehling either alone or in combination with Huber clearly teaches away from the presently claimed invention.

Furthermore, Applicant observes that the hydroxypropylmethyl-celluloses with specific viscosities Huber analyzed gave 39-68% nitrofurantoin release within the first hour (table IV). Wehling on the other hand particularly prefers a much faster release of at least 80% within the first 30 minutes (his column 10, lines 57-62). The skilled person would thus not employ these hydroxypropylmethyl celluloses as the protective material of Wehling, neither in the coating variant nor in the matrix variant. Instant claims 2, 4, 11 and 12 require that the polymer with such viscosities be present in the coating layer or outermost layer of the coating.

As to claim 10, Applicant believes that the release behavior of Huber's layered tablet with two active agent-containing layers cannot give the skilled person a hint about the diffusion behavior of two or more coating layers.

In view of the foregoing, the obviousness rejection of claims 2, 4, and 10-12 should be withdrawn.

### 3. Claims 5 and 13

Claims 5 and 13 are rejected under 35 USC 103(a), as allegedly unpatentable over Wehling and Huber, and further in view of US 5,476,668 (Kobayashi).

Claims 5 and 13 are dependent, directly or ultimately, upon claim 1, which has been amended and are patentable over Wehling and Huber as discussed. Accordingly, claims 5 and 13 also are patentable over Wehling and Huber. Kobayashi does neither disclose nor hint at the features which already were neither disclosed nor hinted at by Wehling or Huber (see above). In view of the foregoing, the obviousness rejection of claims 5 and 13 should be withdrawn.

### 4. Claims 6 and 14

Claims 6 and 14 are rejected under 35 USC 103(a), as allegedly unpatentable over Wehling and Huber, and further in view of US 5,607,697 (Alkire).

Alkire does neither disclose nor hint at the features of amended claim 1, in particular, the combination of ionic polymer with water-soluble acid, sodium hydrogen tartrate, potassium hydrogen tartrate or sodium hydrogen citrate in a particle core coating. Furthermore Alkire also seeks a formulation intended to disintegrate into the mouth to *release* the microparticles (column 3, lines 3-5), which is the opposite of amended claim 1, which requires that the particles be *stuck together* after being moistened with saliva. Thus, Alkire also teaches away from the claimed invention. Accordingly, Applicant respectfully submits that claims 6 and 14 are inventive over the combination of Wehling, Huber, and Alkire, and the obviousness rejection of these claims should be withdrawn.

*Conclusion*

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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